Wake Forest University School of Medicine Clinical and Translational Science Institute
Researcher Classifications and Invoicing Guidelines

Guidance Document for period worked January 1, 2027 through December 31, 2027

This document is intended to provide guidance on the invoicing structure for the Wake Forest University School of Medicine Clinical and Translational Science Institute (CTSI). The guidance will review the pricing calculation, pricing grids, and offer clarification on the following terms as it relates to the invoicing of CTSI services:

a) Researcher Classification,
b) Extramural Award Investigator Status, and
c) Funding Source

A. CTSI Researcher Classifications for North Carolina, Georgia, Illinois, and Wisconsin

- **Faculty Researchers**

  A faculty researcher is defined as an individual with a faculty position:
  - Research Faculty Affiliate**
  - Assistant Professor (Tenure or Non-Tenure)
  - Associate Professor (Tenure or Non-Tenure)
  - Professor (Tenure or Non-Tenure)

  ****Research Faculty Affiliates** are faculty members employed by Advocate/Aurora, Navicent, or Floyd who require access to the WFUSM National Center for Clinical Trials (NCCT) or the Office of Sponsored Programs (OSP). Their primary academic appointment is at an institution other than WFUSM, typically for the purpose of medical education. Individuals holding this rank are actively involved in funded research or clinical trials, which must be conducted in accordance with WFUSM's established processes and policies.

  Faculty Researchers may be classified as **Early-Career** or **Experienced**:
  - **Early-Career Faculty Researchers**
    The Principal Investigator (PI) or the Co-Principal Investigator (Co-PI) of the study must meet one of the criteria to be designated as Early-Career:
    - Research Faculty Affiliate, Tenure Faculty or Non-Tenure Faculty with a rank of Assistant Professor who has never been the PI or Co-PI of an extramural research award exceeding $100,000 in direct costs per year; OR
    - Research Faculty Affiliate, Tenure Faculty or Non-Tenure Faculty with a rank of Assistant Professor currently supported by a career development award (e.g. K23, K08); OR
    - Active CTSI Translational Research Academy member

  - **Experienced Faculty Researchers**
    The Principal Investigator (PI) or the Co-Principal Investigator (Co-PI) of the study is designated as Experienced if they meet the following criteria:
    - Research Faculty Affiliate, Tenure Faculty or Non-Tenure Faculty with a rank of Assistant Professor, Associate Professor, or Professor who has been the PI or Co-PI of an extramural research award exceeding $100,000 in direct costs per year (not currently supported by a career development award (e.g. K23, K08)); OR
    - Research Faculty Affiliate, Tenure Faculty or Non-Tenure Faculty with a rank of Associate Professor or Professor, AND
      - Not currently supported by a career development award (e.g. K23, K08); OR
      - Not an active member of the CTSI Translational Research Academy

- **Non-Faculty Researchers**
  Non-faculty researchers are individuals that can be listed as the Project Lead or, more specifically, the Principal Investigator of an IRB protocol, but are not classified as Research Faculty Affiliate, Tenure or Non-Tenure Track Faculty. A non-faculty researcher is an individual who is in departmental administration or a departmental staff member, or a Faculty Instructor***.

  Individuals that might meet this definition include but are not limited to:

  - Faculty Instructor***
  - Resident
  - Fellow
  - Physician Assistant
  - Nurse Practitioner
  - Pharmacist
  - Physical Therapist (DPT)
  - Nurse Researcher
  - Research Associate
  - Physician

  ***__Faculty Instructor__ is designated for physicians, clinicians, science educators, and APPs who primarily engage in patient care, serve as preceptors, or conduct early-stage research with limited involvement in formal medical education. These roles include part-time or full-time clinical educators, post-doctoral fellows, and early career researchers preparing for future academic advancement. A **Faculty Instructor** may be considered Early Career Faculty if they:
  a) meet the criteria of Early-Career Faculty Researcher, **and**
  b) can provide documentation showing that their initial one to two years of appointment are devoted exclusively to research, serving as a transitional period toward an assistant professorship.

- **Adjunct Faculty**
  Adjunct Faculty are individuals who are not employed by WFUHS, Atrium, Advocate/Aurora, Navicent, or Floyd. These faculty members serve as contract affiliates who contribute to medical education. Typically, they hold primary academic appointments at other institutions. The following titles fall under Adjunct Faculty Appointments:
  - Adjunct Faculty Instructor
  - Adjunct Assistant Professor
  - Adjunct Associate Professor
  - Adjunct Professor

  Adjunct Faculty are not categorized as Faculty or Non-Faculty Researchers and, as such, are not eligible for research services support through the WFUSM CTSI. However, exceptions may be granted if sufficient documentation supports that the individual's affiliation with WFUSM is directly linked to a pilot initiative or externally funded grant activity.

For more detailed information on the types of Appointments, please refer to the **Appointment, Promotion, and Tenure** section of the Office of Faculty Affairs SharePoint Site.

CTSI Researcher Classifications for NC, GA, IL, and WI

Early Career Faculty Researcher

Research Faculty Affiliate, OR
Assistant Professor (Tenure or Non-Tenure)

AND

Has never been the PI or Co-PI of an extramural research award exceeding $100,000 in direct costs per year;

OR

Is currently supported by a career development award (e.g. K23, K08);

OR

Is an Active CTSI Translational Research Academy member.

Experienced Faculty Researcher

Research Faculty Affiliate, OR
Assistant Professor (Tenure or Non-Tenure), OR
Associate Professor (Tenure or Non-Tenure), OR
Professor (Tenure or Non-Tenure)

AND

Has been the PI or Co-PI of an extramural research award exceeding $100,000 in direct costs per year;

-OR-

Research Faculty Affiliate, OR
Associate Professor (Tenure or Non-Tenure), OR
Professor (Tenure or Non-Tenure)

AND

NOT currently supported by a career development award (e.g. K23, K08);

OR

NOT an Active CTSI Translational Research Academy member.

Non-Faculty Researcher

Individuals that can be listed as the Principal Investigator of an IRB protocol, but are not classified as Research Faculty Affiliate, Tenure or Non-Tenure Track Faculty.

Individuals that might meet this definition include:

- Faculty Instructor***
- Resident
- Fellow
- Physician Assistant
- Nurse Practitioner
- Pharmacist
- Physical Therapist (DPT)
- Nurse Researcher
- Research Associate
- Physician

***A Faculty Instructor may be considered Early Career Faculty if they

a) meet the criteria of Early-Career Faculty Researcher, **and**
b) can provide documentation showing that their initial one to two years of appointment are devoted exclusively to research, serving as a transitional period toward an assistant professorship.

Adjunct Faculty

Adjunct Faculty are contract affiliates who contribute to medical education. Typically, they hold primary academic appointments at other institutions.

- Adjunct Faculty Instructor,
- Adjunct Assistant Professor,
- Adjunct Associate Professor, or
- Adjunct Professor

Adjunct Faculty are not categorized as Faculty or Non-Faculty Researchers and, as such, are not eligible for research services support through the WFSOM CTSI. However, exceptions may be granted if sufficient documentation supports that the individual's affiliation with WFUSM is directly linked to a pilot initiative or externally funded grant activity.

Last Updated: 11/25/2026

B. Extramural Award Investigator Status

- **Principal Investigator**
  A Principal Investigator (PI) is defined as the individual who is designated as the lead researcher for a grant. This individual may be a Faculty Researcher or Non-Faculty Researcher and is listed on the IRB protocol. This role is determined at the time of Notice of Award and IRB approval.

- **Co-Principal Investigator**
  A Co-Principal Investigator (Co-PI) is defined as an individual who shares responsibility for the grant with the Principal Investigator. This individual may be a Faculty Researcher or Non-Faculty Researcher and is listed on the IRB protocol. This role is determined at the time of Notice of Award and IRB approval.

- **Contact Principal Investigator**
  A Contact Principal Investigator is responsible for communication between the PI/Co-PI and the funding source. This role is determined at the time of Notice of Award.

C. Funding Sources

- **Federal/Foundation/Association**
  Projects are investigator-initiated and may be funded by a for-profit, non-profit, state, or federal agency. Examples of funding sources include, but are not limited to:
  - Federal – National Institute of Health (NIH), Department of Defense (DoD), PCORI
  - Foundation – Anesthesia Patient Foundation, Burroughs Wellcome Fund, Whitehall Foundation, Michael J Fox Foundation
  - Association – American Diabetes Association, American Heart Association, American Federation for Aging Research

- **Industry Supported**
  Grants and contracts are supported, though the provision of funding, drug, or device, by industry and typically have set costs as agreed through budget negotiations. Examples of industry partners/collaborators include but are not limited to Pfizer, Gilead, and AstraZeneca.

- **Institutional/Unfunded**
  Grants are investigator-initiated and supported by institutional or departmental funding.

- **Institutionally-Supported Center Funded Pilot**
  Request for Applications (RFAs) are released by Institutionally-Supported Research Centers and Institutes for response by Faculty. The RFAs have a target audience with specific parameters that would support the goals of the Center. Grant funding is supported by institutional or departmental funding through the Institutionally-Supported Research Center.

- **CTSI Funded Pilot**
  Request for Applications (RFAs) are released by the Wake Forest CTSI and funding is supported by the CTSA/NCATS grant. The RFAs have a target audience with specific parameters that would support a specific initiative.

- **Enterprise Funded Pilot**
  Request for Applications (RFAs) are released by the Wake Forest CTSI and funding is supported by institutional dollars. The RFAs have a target audience with specific parameters that would support a specific initiative.

D. Additional Guidance

- Pricing is calculated per project, based on the Principal Investigator or Co-Principal Investigator's researcher classification and source of funding as of the date of the service request.
- Pricing will be updated each calendar year.
- Rates will no longer be grandfathered based on a previous year's rates.
    - It is encouraged to include a small amount of inflation in the budget to account for a possible increase in service costs each year.
- The Principal Investigator (Co-Principal Investigator, if applicable) is confirmed at the time of the Notice of Award and cannot be amended unless also amended with the extramural funding source and in the IRB protocol.
    - If there is a discrepancy between the PI noted on the external funding source and the PI noted in the eIRB system, the default is the external funding source.

E. Annual Review

The CTSI Operations team will conduct an annual review of the Pricing Model and Invoicing Guidelines based on the timeline detailed below.

Month	Occurrence
October 2027	• CTSI will conduct an annual review of the PIs of active studies. Any CTSI Researcher Classification changes will be determined at this time.
November-December 2027	• Communication on CTSI Researcher Classification changes will be communicated to the affected PIs. Pricing changes will go into effect January 1, 2028.
November-December 2027	• The CTSI Invoicing Guidelines will be reviewed and updated. CTSI Service Pricing will be recalculated with the Service Line Leaders to be implemented January 1, 2028.
December 2027	• The CTSI Invoicing Guidelines and the CTSI Pricing Grid will be published online for the upcoming calendar year, with an announcement made on the CTSI website.